



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,940	09/08/2004	Dimitrios Pentafragas	U 015325-1	7017

140 7590 03/21/2006

LADAS & PARRY  
26 WEST 61ST STREET  
NEW YORK, NY 10023

EXAMINER
----------

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
----------	--------------

3743

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,940	<b>Applicant(s)</b> PENTAFRAGAS, DIMITRIOS	
	<b>Examiner</b> Teena Mitchell	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/29/05; 12/05/05</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 1, 3-7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Newell et.al. (EPO 0129985).**

With respect to claim 1, Newell discloses an inhalation device which is characterized by the use of a single dose blister strip (Figs. 1, 3, 6, 7, 8), and in that it includes a mouthpiece (9, 28, 35) through which the powder is inhaled, a part with a support surface on which the blister strip is placed in such a manner as to remain securely attached (Figs. 1, 3, 6- 8), and a storage compartment (Fig. 7).

With respect to claim 3, Newell discloses that the mouthpiece contains a projection (Figs. 1, 3, 6-8).

With respect to claim 4, Newell discloses the blister strip support surface includes an attachment point, a cavity, which accommodates the blister and strip guides (Figs. 1, 3, 6-8).

With respect to claim 5, Newell discloses the single dose blister strip is comprised of a base sheet and a cover sheet, which can be separated from each other (Figs. 1, 3, 4, 6, 7).

With respect to claim 6, Newell discloses the base sheet defines a blister that contains the powder and an attachment formation, and in that the cover sheet air-tightly seals the base sheet only in the area of the blister (Figs. 1, 3, 4, 6, 7).

With respect to claim 7, Newell discloses that the exposure of the powder takes place by pulling away the cover sheet from the base sheet (Fig. 4).

With respect to claim 8, Newell discloses a base sheet and a cover sheet, said sheets being air tightly sealed to one another, in that said base sheet defines a powder containing blister and an attachment formation and in that the cover sheet covers the base sheet around the blister and can be detached from the base sheet (Figs. 1, 3, 4, 6, 7).

With respect to claim 9, Newell discloses a blister strip support surface for a dry powder inhalation device characterized by an attachment point, a cavity which accommodates the blister and strip guides (Figs. 1, 3, 4, 6, 7).

### ***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

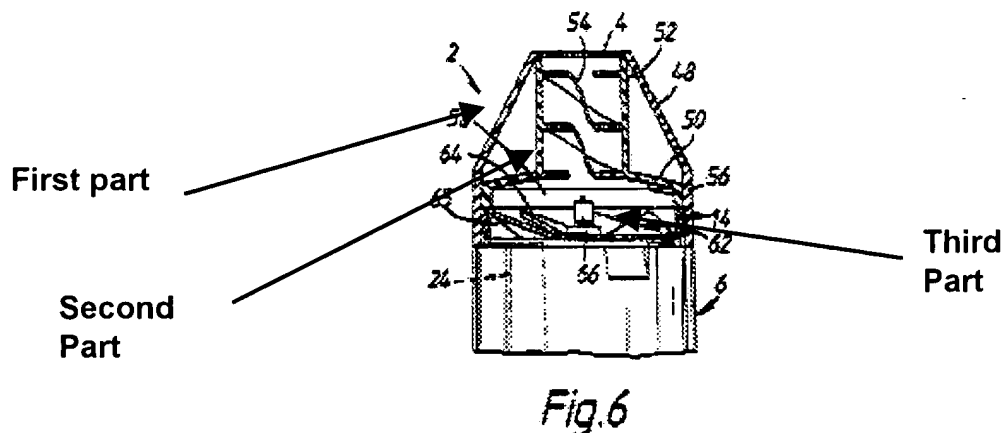
**The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:**

Art Unit: 3743

1. **Determining the scope and contents of the prior art.**
2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

**Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newell et.al. (EPO 0129985) in view of Andersson et.al. (6,257,232).**

The difference between Newell and claim 2 is the mouthpiece comprised of three parts, which are lockable to each other. Andersson in an inhalation device teaches a mouthpiece of three parts which are lockable to each other (see illustration of Fig. 6 below). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the mouthpiece of Newell with any well known mouthpiece including the three part mouthpiece of Andersson doing so would have provided a mouthpiece which helps break the medicament particles finer, prior to inhalation by a user of the device.




Art Unit: 3743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Teena Mitchell  
Primary Examiner  
Art Unit 3743  
March 14, 2006

  
TKM